LAW OFFICES

HYMAN, PHELPS & MCNAMARA, P.C.

JAMES R. PHELPS PAUL M. HYMAN ROBERT A DORMER STEPHEN H. MCNAMARA ROGER C. THIES THOMAS SCARLETT JEFFREY N. GIBBS BRIAN J DONATO FRANK J. SASINOWSKI DIANE B McCOLL A. WES SIEGNER, JR. ALAN M. KIRSCHENBAUM DOUGLAS B. FARQUHAR JOHN A GILBERT, JR. JOHN R FLEDER MARC H. SHAPIRO FRANCES K. WU JEFFREY N WASSERSTEIN ROBERT T ANGAROLA (1945-1996)

700 THIRTEENTH STREET, N W SUITE 1200 WASHINGTON, D. C. 20005-5929

(202) 737-5600

FACSIMILE (202) 737-9329

www.hpm.com

JENNIFER B. DAVIS OF COUNSEL

DAVID B. CLISSOLD
CASSANDRA A. SOLTIS
JOBEPHINE M TORRENTE
MICHELLE L. BUTLER
ANNE MARIE MURPHY
PAUL L. FERRARI
LARRY K. HOUCK
DARA S. KATCHER*
KURT R. KARST
SHAWN M BROWN*
JULIE C. KLISH*
CHRISTINE P BUMP*

NOT ADMITTED IN DC

DIRECT DIAL (202) 737-4291

January 19, 2005

BY FACSIMILE/CONFIRMATION COPY BY FEDERAL EXPRESS

Division of Dockets Management Food and Drug Administration 5630 Fishers Lane, Room 1061 HFA-305 Rockville, MD 20852

Re: 2004P-0485/CP1

Dear Sir/Madam:

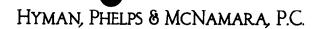
On behalf of a client, Hyman, Phelps & McNamara, P.C. submits these comments on the citizen petition (hereinafter "the Petition") submitted by Kirkpatrick & Lockhart LLP (hereinafter "the Petitioner"), which requests that the Food and Drug Administration (FDA) amend the nutrition labeling regulation for dietary supplements to require that the source of the dietary ingredient lycopene be identified in the Supplement Facts box. As explained below, this proposed change would cause the labels of some dietary supplements containing lycopene to be misleading, and it may imply that lycopene derived from natural sources is superior to synthetic lycopene, in violation of 21 C.F.R. §§ 101.9(k)(4), 101.36(j). In addition, it would be unfair and unreasonable to impose this requirement only on dietary supplements containing lycopene.

At the outset, we wish to point out an apparent inconsistency in the purpose of this Petition. The Petition requests that 21 C.F.R. § 101.36(d)(1) be revised simply to require that "the source of the dietary ingredient lycopene" be identified whether the source is botanical, synthetic, or fungal. Petition at 1. Subparagraph (d)(1) of 21 C.F.R. § 101.36 is

50016-0182

2603 MAIN STREET SUITE 760 IRVINE. CALIFORNIA 92614 (949) 553-7400 FAX (949) 553-7433

4819 EMPEROR BOULEVARD SUITE 400 DURHAM, NORTH CAROLINA 27703 1919) 313-4750 FAX (919) 313-4751



Division of Dockets Management January 19, 2005 Page 2

to be read in conjunction with paragraph (d) of that same section, which provides that the source ingredient of a dietary ingredient must be listed in <u>either</u> the Supplement Facts box or the ingredient declaration. 21 C.F.R. § 101.36(d) ("When a source ingredient is not identified within the nutrition label, it shall be listed in an ingredient statement in accordance with § 101.4(g)....").

The Petition's conclusion, however, appears to request that the nutrition label (<u>i.e.</u>, the <u>Supplement Facts box</u>) always identify the source ingredient of lycopene:

The Petitioner requests that the Commissioner of Food and Drugs amend FDA's regulation at 21 C.F.R. § 101.36(d)(1) to require [that] the nutrition label inform the consumer of the source of the dietary ingredient contained in the dietary supplement. Specifically, Petitioner requests that, in dietary supplements containing lycopene, the nutrition label on a dietary supplements [sic] should identify that the source of the lycopene is either "from tomato," "from fungus," or "synthetic."

Petition at 12.

The Petitioner's request to change subparagraph (d)(1) would not alter (d), which gives companies the option to list the source ingredient either in the Supplement Facts box or the ingredient declaration. Thus, the Petitioner's requested change does not appear to accomplish the Petitioner's goal of requiring the source ingredient for lycopene to be declared in the Supplement Facts box.

Nevertheless, for the purpose of these comments, we will assume that the Petitioner's requested change would effectuate its objective of having the source ingredient for lycopene always be declared in the Supplement Facts box.

I. Identifying the Source of Lycopene in the Supplement Facts Box May Be Misleading

Certain dietary supplements may be misbranded under Section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (FDC Act) if FDA were to require that the source of lycopene, whether from a botanical or not, be identified in the Supplement Facts box. Under the current pertinent FDA regulation, a source ingredient must be identified in either

HYMAN, PHELPS & MCNAMARA, P.C.

Division of Dockets Management January 19, 2005 Page 3

the Supplement Facts box or the ingredient declaration. 21 C.F.R. § 101.36(d)(1). However, a source ingredient is identified in the Supplement Facts box or the ingredient declaration only if the source itself is an <u>ingredient</u> in the product.

Several FDA statements, both before and after the enactment of the Dietary Supplement Health and Education Act of 1994 (DSHEA), support the proposition that source ingredients of dietary ingredients are to be identified in either the nutrition label or the ingredient statement only if the source ingredients are present in the product. In a pre-DSHEA proposed rule on nutrition labeling of dietary supplements, FDA prohibited the identification of source ingredients in the nutrition label because "[c]onsumers desiring to know the source of a nutrient can merely look at the list of ingredients, just as they would for a food in conventional food form." 58 Fed. Reg. 33,715, 33,720 (June 18, 1993) (Proposed Rule: General Requirements for Nutrition Labeling for Dietary Supplements of Vitamins, Minerals, Herbs, or Other Similar Nutritional Substances) (emphasis added). The pre-DSHEA final rule also prohibited the identification of source ingredients in the nutrition label and maintained that source ingredients are to be identified in the ingredient declaration. 59 Fed. Reg. 354, 364 (Jan. 4, 1994) (Final Rule: General Requirements for Nutrition Labeling for Dietary Supplements of Vitamins, Minerals, Herbs, or Other Similar Nutritional Substances).

Post-DSHEA, FDA proposed a rule for the labeling of dietary supplements that required source ingredients to be identified in either the nutrition label or the ingredient statement. 60 Fed. Reg. 67,194, 67,217 (Dec. 28, 1995) (Proposed Rule: Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements). FDA statements in this proposal suggest that, to the extent that the source ingredients are declared, the source ingredients must be present in the product:

[T]he source of any dietary ingredient (i.e., the <u>ingredient</u> supplying the dietary ingredient) may be added in parentheses immediately following or indented beneath the name of the dietary ingredient.

Id. at 67,203 (emphasis added);

The DSHEA uses the term "dietary ingredient" to refer to the primary substances to be listed in nutrition labeling, as opposed to "ingredients" that are the compounds used in the manufacture of the product. For instance, when calcium carbonate is an ingredient used to provide calcium in the manufacture of a dietary supplement,

HYMAN, PHELPS & MCNAMARA, P.C.

Division of Dockets Management January 19, 2005 Page 4

calcium is the "dietary ingredient," and calcium carbonate is the "ingredient," or, as specified in the new section 403(q)(5)(F)(iii) of the act, the "source of" the dietary ingredient.

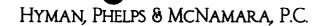
Id. at 67,199 n.2.

FDA statements in the post-DSHEA final rule also support this notion. 62 Fed. Reg. 49,826 (Sept. 23, 1997) (Final Rule: Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements). In the final rule, FDA reasoned that parentheses around source ingredients appearing in the Supplement Facts box were necessary so that consumers would understand that the weight and the percent daily value declared pertain to the dietary ingredient and not to the source ingredient. Id. at 49,835. In addition, the final rule adopted the proposed rule's requirement that "[w]hen source ingredients are listed within the nutrition label, and two or more are used to provide a single dietary ingredient, all of the sources shall be listed within the parentheses in descending order by weight." Id. at 49,851 (codified as 21 C.F.R. §101.36(d)(2)). These requirements establish that source ingredients must be present in the product.

Accordingly, under 21 C.F.R. § 101.36(d), source ingredients cannot be declared in either the Supplement Facts box or the ingredient declaration if the dietary ingredient is extracted from the source ingredient and, therefore, only the dietary ingredient is present in the product. For example, if lycopene is extracted from tomato such that only lycopene, and not tomato, is present in the product, then only lycopene can be declared in the Supplement Facts box (and/or may be declared in the ingredient declaration). If tomato is not present in the product, then tomato cannot be declared in the Supplement Facts box or the ingredient declaration. Declaring tomato in either the Supplement Facts box or ingredient statement would be misleading because it would imply that the product contains tomato when it does not.

II. Identifying the Source of Lycopene Might Imply That Natural Lycopene Is Superior to Synthetic Lycopene

FDA's longstanding regulation provides that "[a] food labeled under the provisions of this section shall be deemed to be misbranded under sections 201(n) and 403(a) of the act if its label or labeling represents, suggests, or implies . . . [t]hat a natural vitamin in a food is superior to an added or synthetic vitamin." 21 C.F.R. §§ 101.36(j), 101.9(k)(4). Requiring that the source of lycopene always be identified in the Supplement Facts box might imply that natural lycopene is superior to synthetic lycopene, especially since the



Division of Dockets Management January 19, 2005 Page 5

"source" of synthetic lycopene has never been (and cannot appropriately be) identified in the Supplement Facts box or ingredient statement. Consumers might interpret this change in labeling as a signal that synthetic lycopene is inferior to natural lycopene, in violation of 21 C.F.R. §§ 101.36(j), 101.9(k)(4).

III. If FDA Approves the Petition, Then All Source Ingredients for All Dietary Ingredients Should Be Identified in the Supplement Facts Box

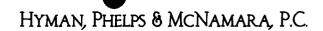
It would be misleading and unfair to require that only the source of lycopene be identified in the Supplement Facts box. It would confuse or mislead consumers into believing there is something special about lycopene. Furthermore, lycopene would be the only dietary ingredient whose source must be identified in the Supplement Facts box even though the source ingredient is not always present in the product. Accordingly, if FDA approves the Petition, FDA should require that <u>all</u> source ingredients from which dietary ingredients are derived be identified in the Supplement Facts box.

As noted in Part I above, it is unclear how this can be accomplished without making dietary supplement labels misleading because not all source ingredients of dietary ingredients are present in dietary supplement products.

IV. The Petition's Proposed Change to the Nutrition Labeling of Dietary Supplements Is Unnecessary Because FDA Has the Enforcement Mechanisms Necessary to Stop Misleading Labeling

The Petition's proposed change is unnecessary because FDA has the ability to take enforcement action against dietary supplements that bear misleading labeling. Under the FDC Act, a food is misbranded if "its labeling is false or misleading in any particular." FDC Act § 403(a)(1). The FDC Act prohibits misbranded foods from being introduced or delivered into interstate commerce. Id. § 301(a). As the Petitioner noted, a food label that depicts tomatoes but does not contain tomatoes is arguably misleading because consumers would expect that tomatoes are in the product. Because FDA already has a means to address such misleading labeling, it is unnecessary to revise the regulation.

Moreover, as noted above, referring to tomatoes as the source where tomatoes are not present in the product would be false and misleading.



Division of Dockets Management January 19, 2005 Page 6

V. Conclusion

FDA should deny the Petition because the Petitioner's requested change to the nutrition labeling regulation of dietary supplements would lead to misleading labeling and would imply that synthetic lycopene is inferior to natural lycopene, in violation of FDA regulations. Furthermore, the request is unnecessary because FDA has a means to take action against misleading dietary supplement labels. However, if FDA approves the Petition, FDA should impose on all dietary ingredients the requirement that their sources be identified in the Supplement Facts box.

Respectfully submitted,

Diani B. McCel/CAR

Diane B. McColl

DBM/vam